HIPAA/STATE LAW PREEMPTION ANALYSIS METHODOLOGY

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EXPLANATION

The following preemption analysis methodology outline includes a statement of the general rule of HIPAA preemption of State law, key preemption definitions and a preemption analysis methodology. The preemption methodology is a tool designed to assist persons and entities covered by the Health Insurance Portability and Accountability Act (HIPAA) in analyzing provisions of State law for preemption by HIPAA. The preemption analysis methodology should be used in conjunction with the "Preemption Analysis Template" document posted on the CalOHI website under "Preemption Tools".

The preemption analysis methodology set forth here is the methodology used by CalOHI to prepare its HIPAA/State law preemption analyses.

Please forward any comments, corrections, etc. to the attention of:

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PREEMPTION ANALYSIS METHODOLOGY

PREEMPTION GENERAL RULE:

"A standard, requirement, or implementation specification adopted under [Subchapter C of Subtitle A of Title 45 of the Code of Federal Regulations] that is contrary to a provision of State law preempts the provision of State law. This general rule applies , except if one or more [of the exceptions applies]." (45 C.F.R. § 160.203.)

PREEMPTION DEFINITIONS:

"STATE LAW":

"State law" means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law. (45 C.F.R. § 160.202 (definition of "State law").)

"RELATES TO THE PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION":

"Relates to the privacy of individually identifiable health information" means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way. (45 C.F.R. § 160.202 (definition of "Relates to the privacy of individually identifiable health information").)

ANALYZING STATE LAW FOR REEMPTION:

STEP ONE—Determine Whether the State Law Provision is Within One or More of the Non-Section 1178(a)(2)(B) Statutory Carve-Outs From HIPAA:

HIPAA provides for exceptions from preemption analysis. These "carve-out" exceptions are set forth in Section 1178 of the Social Security Act. The primary carve out is in Section 1178(a)(2)(B) (see step 2 below). The other carve outs are in Sections 1178(a)(2)(A), 1178(b) and 1178(c). These "non-Section 1178(a)(2)(B) carve outs", if applicable, save the State law from preemption by HIPAA, and thus no further HIPAA preemption analysis is required and the State law must be followed, only, and not the analogous HIPAA provision(s). The following are the non-Section 1178(a)(2)(B) carve outs:

1. An exception determination regarding the State law has been made by the Secretary of Federal HHS pursuant to Title 45 of the Code of Federal Regulations, section 160.204 (see discussion below of exception determinations). (45 C.F.R. § 160.203(a).) [NOTE: No such exception determinations have been made concerning California State law as of January 9, 2003.]

2. The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention. (45 C.F.R. § 160.203(c).)

3. The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals. (45 C.F.R. § 160.203(d).)

STEP TWO— Determine Whether the State Law Provision is Within the Section 1178(a)(2)(B) Statutory Carve-Out From HIPAA:

STEP TWO (1st Test)— Determine Whether the State Law Provision is "Contrary" to HIPAA:

If the provision State law is not within a non-Section 1178(a)(2)(B) "carve out", then it must be determined in a two-part test whether the provision of State law—which must "relate to the privacy of individually identifiable health information" (see definition above) - is a Section 1178(a)(2)(B) carve out. The first test is whether the provision is "contrary" to HIPAA requirements. "'Contrary', when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under [Subchapter C of Subtitle A of Title 45 of the Code of Federal Regulations—the administrative simplification part of HIPAA], means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104-191, as applicable." (45 C.F.R. § 160.202 (definition of "contrary").)

If the State law is contrary to HIPAA, go to the second test of the Section 1178(a)(2)(B) carve out analysis. If the State law is not contrary to HIPAA it is not preempted and must be followed, only, and not the analogous HIPAA provision(s).

STEP TWO (2nd Test)— Determine Whether the Contrary State Law Provision is "More Stringent" than HIPAA:

If the provision of State law is contrary to any HIPAA requirement(s) regarding individually identifiable health information, then it must be determined whether the provision of State law is "more stringent" than corresponding HIPAA requirements. Provisions of State law that are more stringent than HIPAA will not be preempted by HIPAA and must be followed, only, and not the analogous HIPAA provision(s). State laws which are contrary and not more stringent than HIPAA requirements will be preempted by HIPAA, in which case HIPAA alone must be followed and not the analogous State law. Pursuant to HIPAA, "[m]ore stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under Subpart E of part 164 of [Subchapter C of Subtitle A of Title 45 of the Code of Federal Regulations], a State law that meets one or more of the following criteria:"

1. "With respect to a use or disclosure, the law prohibits or restricts a use or disclosure of individually identifiable health information in circumstances under which such use or disclosure otherwise would be permitted under [Subchapter C of Subtitle A of Title 45 of the Code of Federal Regulations], except if the disclosure is: (i) Required by the Secretary [of Federal HHS] in connection with determining whether a covered entity is in compliance with [Subchapter C of Subtitle A of Title 45 of the Code of Federal Regulations]; or (ii) To the individual who is the subject of the individually identifiable health information." (45 C.F.R. § 160.202 (definition of "more stringent", subsection (1)).)

2. "With respect to the rights of an individual who is the subject of the individually identifiable health information of access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable." (45 C.F.R. § 160.202 (definition of "more stringent", subsection (2).)

3. "With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information." (45 C.F.R. § 160.202 (definition of "more stringent", subsection (3)).)

4. "With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect

of the circumstances surrounding the express legal permission, as applicable." (45 C.F.R. § 160.202 (definition of "more stringent", subsection (4)).) [Note: This section may be amended by the March 18 NPRM.]

5. "With respect to record keeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration." (45 C.F.R. § 160.202 (definition of "more stringent", subsection (5)).)

6. "With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information." 45 C.F.R. § 160.202 (definition of "more stringent", subsection (6)).)

STEP THREE—Determine Controlling Law:

In light of the foregoing analyses, determine the controlling law. Follow only the State law provision if:

1. The State law provision is saved from preemption by one or more Section 1178 carve-outs; or
2. The State law provision is not contrary by virtue of the "required by law" provision of HIPAA (and is not in a "required by law" category with additional HIPAA requirements).

Follow only the HIPAA provision if the State law provision is preempted, i.e., it is contrary and not more stringent than the corresponding HIPAA requirement.

Follow the State law provision and HIPAA requirement if the State law provision is not contrary to HIPAA (but not by virtues of a 1178 carve out), e.g., when there is no analogous HIPAA provision.

STEP FOUR—Determine Whether There is a Basis for an Exception Determination:

The State may, through the Governor, request an "exception determination" from Federal HHS, with respect to a particular law, under the following circumstances:

1. A determination is made by the Secretary of Federal HHS that the provision of State law is necessary:

a. To prevent fraud and abuse related to the provision of or payment for health care. (45 C.F.R. § 160.203(a)(1)(i).)

b. To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation. (45 C.F.R. § 160.203(a)(1)(ii).)

c. For State reporting on health care delivery or costs. (45 C.F.R. § 160.203(a)(1)(iii).)

d. For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served. (45 C.F.R. § 160.203(a)(1)(iv).)

2. A determination is made by the Secretary of Federal HHS that the provision of State law has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of controlled substance (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law. (45 C.F.R. § 160.203(a)(2).)